

OCT 18 2000

K002700

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of the Safe Medical Devices Act (SMDA) of 1990 and 21 CFR 807.92. All data included in this document is accurate and complete to the best of KSEA's knowledge.

Applicant: Karl Storz Endoscopy - America, Inc.
600 Corporate Pointe Drive
Culver City, CA 90230
(310) 558-1500

Contact: Marika Anderson
Senior Regulatory Affairs Specialist

Device Identification: **Common Name:**
Suction Pump

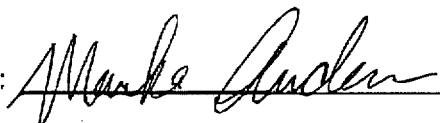
Trade Name: (optional)
Karl Storz Unimat 12

Indication: The Karl Storz Unimat 12 system is designed to provide aspiration of the surgical site during general and endoscopic ENT surgical procedures.

Device Description: The Karl Storz Unimat 12 and accessories are an aspiration pump with user adjustable aspiration suction underpressure.

Substantial Equivalence: The Karl Storz Unimat 12 system is substantially equivalent to the predicate devices since the basic features and intended uses are similar (see attached table). The minor differences between the Karl Storz Unimat 12 and the predicate devices raise no new issues of safety and effectiveness, as these differences have no effect on the performance, function or intended use of these devices.

Signed:



Marika Anderson
Senior Regulatory Affairs Specialist

**SUBSTANTIAL EQUIVALENCE CHART FOR KARL STORZ UNIMAT PLUS
TO PROVIDE IRRIGATION/ASPIRATION**

Features	Karl Storz Unimat 12	Karl Storz Unimat Plus (K962898)	Karl Storz Unimat (K953190)
Type of Pump	Microprocessor controlled aspiration pump	Membrane type irrigation/aspiration pump	Microprocessor controlled aspiration pump
Maximum suction underpressure	-0.8 bar 600 mm Hg	-0.75 bar	-0.8 bar 600 mm Hg
Flow rate	0 to 2.0 liters/minute	0 to 3.5 liters/minute	0 to 2.0 liters/minute
Intended Use	To provide aspiration of the surgical site during general and endoscopic ENT surgical procedures	To provide irrigation / aspiration of the surgical site during general and endoscopic ENT surgical procedures	To provide aspiration of the surgical site during laparoscopic surgical procedures in gynecology



OCT 18 2000

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Kevin Kennan
Sr. Regulatory Affairs Specialist
Karl Storz Endoscopy
600 Corporate Pointe
Culver City, CA 90230

Re: K002700
Trade Name: KSEA Unimat 12
Regulatory Class: II
Product Code: 77 EOB, 77 EOQ
Dated: August 21, 2000
Received: August 30, 2000

Dear Mr. Kennan:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

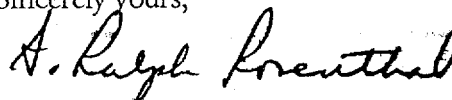
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Page 2 - Mr. Kevin Kennan

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-6413. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink that reads "A. Ralph Rosenthal". The signature is written in a cursive style with a large, stylized "A" and "R".

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

K002700

510(k) Number (if known):

Device Name: Unimat 12

Indications for Use: These instruments are intended for use by qualified surgeons and provide aspiration of fluid from the surgical site during general and endoscopic ENT surgical procedures.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: ☒ OR Over-The-Counter Use: ☐
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Karen H. Brown
(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K002700

[Handwritten signature]